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EXAMINER	
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ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/559,610	FILICORI, MARCO	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 September 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,8,11-21,25,26,29-34,36-38,40,41 and 44-49* is/are pending in the application.

4a) Of the above claim(s) *21,25,26,29-33,38,40 and 41* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,7,8,11-20,34,36,37 and 44-49* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/22/08, 11/26/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 22 September 2008, have been entered in full.

Claims 21, 25, 26, 29-33, 38, 40, 41 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected Group. Claims 2-6, 9, 10, 22-24, 27, 28, 35, 39, 42, 43 are canceled. New claims 48 and 49 were added. Claims 1, 7, 8, 34, 44-47 were amended.

Claims 1, 7, 8, 11-20, 34, 36, 37, 44-49 are under examination.

Information Disclosure Statement

The information disclosure statement(s) (IDS) (filed 22 September 2008 and 26 November 2008) were received and comply with the provisions of 37 CFR §§1.97 and 1.98. They have been placed in the application file and the information referred to therein has been considered as to the merits. All of the Office Actions listed on the IDS have been considered.

Withdrawn Objections And/Or Rejections

The rejection to claim 19 under 35 U.S.C. 112, second paragraph, as set forth at page 10 of the previous Office Action (21 March 2008), is *withdrawn* in view of Applicant's argument (filed 22 September 2008). **Please see the new 35 U.S.C. 112, Second paragraph rejection for claim 19 below.**

The rejection of claims 1-15, 19, 20, 34-37 and 43 under 35 U.S.C. 103(a) as being unpatentable over Skrabanja et al., US Patent No. 5,656,597 in view of Menezo, WO 03/022303 A2, as set forth at pages 4-7 of the previous Office Action (21 March 2008), is *withdrawn* in view of the amendment which changes the IUs of FSH and hCG (filed 22 September 2008).

The rejection to claims 1, 2, 11-20, 34-37, 46 and 47 under 35 U.S.C. 103(a) as being unpatentable over Skrabanja et al., US Patent No. 5,929,028 in view of Cui et al., United States Patent Application Publication US 2004/0142887 A1, as set forth at pages 7-10 of the previous Office Action (21 March 2008), is *withdrawn* in view of Applicant's argument that Cui administers hCG as an antigenic contraceptive vaccine, thus inducing antibodies against hCG to prevent pregnancy and the amendment which changes the IUs of FSH and hCG (filed 22 September 2008).

The objection to claims 8, 42 and 43, as set forth at page 10 of the previous Office Action (21 March 2008), is *withdrawn* in view of the amendment (filed 22 September 2008).

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 20 and 36 (and new claim 48) remain rejected under 35 U.S.C. 112, second paragraph. The basis for this rejection is set forth at page 3 of the previous Office Action (21 March 2008).

Applicant argues that claims 20 and 36 further limit claims 19 and 34, respectively, by reciting that the assemblage or product further includes instructions, which is not required by claims 19 or 34. Applicant argues that it not necessary to specify the format of the instructions.

Applicant's arguments have been fully considered but are not considered. The instant claims are indefinite because it is not know what physical form (i.e. paper, label, CD, etc.) the instructions must take. Thus, the metes and bounds of the instant claims cannot be determined. The scientific reasoning and evidence as a whole indicates that the rejection should be maintained.

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 44 remains rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: "wherein the amount of hCG in the second pharmaceutical composition is **between** 0.04 and 16 ug" (claim 44). The Examiner has located the following limitation "0.04, 0.2, 0.4, 1, 2, 3, 4, 8, 12 **OR** 16 ug hCG" in Figure 1B. The Examiner has not located the limitation, "**between** 0.04 and 16 ug". The basis for this rejection is set forth at pages 3-4 of the previous Office Action (21 March 2008).

Applicant cites MPEP 2163 and case law. Applicant argues that the skilled artisan seeing Figure 1B would understand that the range 0.04-16 ug hCG was part of the invention.

Applicant's arguments have been fully considered but are not found persuasive. The Examiner takes no issue with the cited MPEP and case law. However, the limitation, "between 0.04 and 16 ug" now encompasses ug hCG numbers such as 0.05, 0.07, 13 ug hCG, for example. By changing the limitation to explicitly recite, "between 0.04 and 16 ug", Applicant has included more ug hCG numbers, which **were not** contemplated in the specification as orginally filed. The new limitation changes the scope of disclosure and the scope of that which was contemplated at the time of filing, thus resulting in new matter. The new limitation, "**between** 0.04 and 16 ug", renders the claim broader than the original disclosure (i.e. "0.04, 0.2, 0.4, 1, 2, 3, 4, 8, 12 **OR** 16 ug hCG", as recited in Figure 1B).

The scientific reasoning and evidence as whole indicates that the rejection should be maintained.

NEW CLAIM REJECTIONS/OBJECTIONS

Claim Rejections - 35 USC § 112, Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7 and 19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 7 recites the limitation "50 IU FSH and 400 IU hCG". Claim 7 depends from claim 1. There is insufficient antecedent basis for this limitation in the claim.

Regarding claim 19; Applicant argues that claim 19 depends from claim 1, which recites compositions with differing amounts of FSH and hCG and that these compositions inherently have ratios of FSH and hCG. Applicant argues against the Examiner's assertion that claim 19 lacks antecedent support for the "ratio of FSH to hCG". Applicant argues that compositions comprising 50 IU FSH and 100 IU hCG have a FSH:hCG ratio of 1:2. Applicant argues that compositions comprising 50 IU FSH and 200 IU hCG have a FSH:hCG ratio of 1:4. Applicant argues that those skilled in the art will understand the ratio of FSH to hCG for each of the embodiments recited in claim 1 and will readily understand what is meant by "the ratio of FSH to hCG" as recited in claim 19.

Applicant's arguments have been fully considered but are not deemed persuasive. Those skilled in the art would understand the limitation "amount" (i.e. claim 1) to mean quantity and the limitation "ratio" (i.e. claim 19) to mean a mathematical relation of proportion. If understood as the limitation "ratio" (i.e. 50 IU FSH and 100 IU hCG has a FSH:hCG ratio of 1:2 as stated by Applicant), then the numbers as taught in the instant specification, **specifically paragraph 0021**; would be redundant because 75 IU FSH and 75 IU hCG and 100 IU FSH and 100 IU hCG are both 1:1 ratios. Numbers

recited in paragraph 0021 such as 150 IU FSH and 300 IU hCG and 200 IU FSH and 400 IU of hCG both have 1:2 ratios. The metes and bounds cannot be determined according to Applicant's argument.

It is noted by the Examiner that the attorney of record (Courtenay C. Brinckerhoff) stated **the exact opposite argument** for the limitations, "amounts" and "ratios" in the related application 11/898,470. Please see page 9 (last paragraph) of Applicant's Remarks (submitted 11/13/07) for related application 11/898,470.

Claim Rejections-35 USC § 112, First Paragraph, Written Description (New Matter)

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 37, 45 and 47 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed:

"further comprising a means for administering the first and second pharmaceutical composition" (claim 37)

"wherein the amount of FSH....is from about **1.0 ug** to about 2,000 mg/ml (claims 45 and 47).

Applicant's amendment, filed 30 November 2007, asserts that no new matter has been added and directs support to paragraph 0057 for the written description for the above-mentioned "limitations".

The Examiner has located the following limitation, "Expressed in proportions, FSH and hCG each are generally present in from about **0.1 ug** to about 2,000 mg/ml" (paragraph 0057).

The Examiner has not located the limitation, "about **1.0 ug** to about 2,000 mg/ml. The wording or connotation of the instant claim(s) is not readily apparent from said sections. The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed.

The Examiner has located the following teaching, "the product can be supplied in any appropriate package. For example, **a product can contain a number of pre-filled syringes containing either FSH, hCG, or a combination of both FSH and hCG**, the syringes packaged in a blister package or other means to maintain sterility" (paragraph 0053)

The limitation "further comprising a means for administering..", as recited in claim 37, renders the claim broader than the original disclosure, which teaches syringes. The limitation changes the scope of disclosure and the scope of that which was contemplated at the time of filing, thus resulting in new matter.

Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide **specific written support** for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Rejections-35 USC § 102(b)

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 11-16, 19, 20, 34, 36, 44, 46, 48 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Filicori et al. (Fertility and Sterility, Vol. 72, No. 6, Dec. 1999). Filicori et al. teach the administration of 75-150 IU FSH with 50 IU hCG to induce folliculogenesis (abstract and page 1119, 4th full paragraph and page 1120)(**applies to claims 1, 19 and 49**). Filicori et al. teach that the FSH is the brand name Metrodin and that hCG is the brand name Profasi (page 1119, 3rd full paragraph). Metrodin is taught as a gonadrotropin extracted from the urine of postmenopausal women comprising FSH which is produced in a lyophilized form (see Appendix A). Profasi is taught as a gonadotropin extracted from the urine of postmenopausal women which is produced in a lyophilized form (see Appendix B). In addition, 5,000 IU of Profasi urinary hCG (u-hCG) is taught as being equivalent to 250 ug of recombinant hCG (r-hCG)(see Butler, Fertility & Sterility, Vol. 80, No. 6; page 1533; December

2003). Thus, Filicori et al. teach the use of 2.5 ug of hCG (**applies to claims 34, 44 and 46**). Because FSH and hCG was administered to patients via injection, it must be in liquid form at some point (**applies to claims 11-16**). Since commercial gonadotropins were used, the vials would have written instructions regarding timing for administering the compositions (**applies to claims 20 and 36**). Filicori et al. teach that FSH was administered throughout treatment and supplemented with hCG (page 1119)(**applies to claim 48**). Claims 20, 36 and 48 does not recite the physical form of the written instructions (i.e. paper, label, etc), thus instant reference meets the claim limitation.

Claims 1, 11, 13-16, 19, 20 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (reference submitted by Applicant; Fertility and Sterility, Vol. 63, No. 2, Feb 1995). Thompson et al. teach the administration of 150 IU FSH with 50 to 75 IU hCG to induce folliculogenesis (abstract) (**applies to claims 1, 19 and 49**). Thompson et al. teach that the FSH is the brand name Metrodin (page 274, 2nd paragraph). Because FSH and hCG was administered to patients via injection, it must be in liquid form at some point (**applies to claims 11, 13-16**). Since commercial gonadotropins were used, the vials would have written instructions regarding timing for administering the compositions (**applies to claim 20**). Claim 20 does not recite the physical form of the written instructions (i.e. paper, label, etc), thus instant reference meets the claim limitation.

Claims 1, 7, 8, 11, 13, 16, 19 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Menezo (reference of record; WO 03/022303 A2). Menezo teaches methods of administering gonadotropins for improved implantation rates (page 3, lines 30-37). **Menezo teaches a kit comprising doses of FSH and hCG (claim 31).** Menezo teach the use of hCG for the manufacture of a medicament for use in conjunction with controlled ovarian hyperstimulation (COH) in human patients using FSH (page 4, lines 15-24) and a pharmaceutical composition for use in aiding implantation of an embryo, optionally and preferably in conjugation with COH, comprising 25-1000 IU hCG (page 4, lines 31-35). Menezo teaches 75-200 or 150 IU FSH and 25-1000 IU or 50-100 IU of hCG (page 6, lines 20-34)(**applies to claims 1, 7, 8, 13, 19 and 49**). Menezo et al. teach that when hCG is used in the aspects of the invention, the dosage should be in the range of 25-4000 IU, preferable 25-1000, more preferably 30-1000 or 30-500 IU and particularly preferably 50-100 IU or 75-125 or 75-100 IU or 75 or 100 or 500 or 75 or 100 to 1000 IU (page 8, lines 24-31 and page 9, lines 21-35). Menezo et al. teach that aspects of the invention are used in conjunction with COH regimens; FSH may be administered at or about 75 to 250 or 75 to 200 IU, preferably at or about 150 to 200 IU (page 11, lines 5-20))(**applies to claims 1, 7, 8, 13, 19**). Menezo teaches the use of urinary or recombinant hCG (page 16, lines 1-5). Menezo teaches the use of urinary or recombinant FSH (page 18, lines 1-9)(**applies to claim 11**). Because FSH and hCG is administered to patients via injection, it must be in liquid form at some point (**applies claim 16**).

Claim 45 is rejected under 35 U.S.C. 102(b) as being anticipated by Skrabanja et al. (reference of record; US Patent No. 5,929,028)

Skrabanja et al. teach that the invention resides in a method of treating infertility by the administration of gonadotropins (column 50-57). Skrabanja et al. teach gonadotropin-containing formulations comprising FSH or hCG or mixtures thereof (abstract; column 3, lines 15-26; column 3, lines 59-65; column 4, lines 22-30). Skrabanja et al. teach methods of admixing in an aqueous solution at least one gonadotropin (column 5, lines 62-67). Skrabanja et al. teach that FSH doses ranges from about 25 to 1500 IU, especially 5-225. Skrabanja et al. teach that as high as 10,000 IU and as low as 15 IU of hCG have been administered. Skrabanja et al. teach that suitable concentrations of FSH ranges from about 20-2000 IU/ml, which roughly corresponds with a concentration of 2-200 ug/ml (column 6, lines 23-41)(**applies claim 45**). Skrabanja et al. that the formulation may be supplied in cartridges, ampoule, vials, bottles or bags and that the cartridge may contain an amount of the liquid gonadotropin formulation corresponding to one or more therapeutic dosages (column 6, lines 56-67 and claims).

Claim Rejections-35 USC § 103(a)

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17, 18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Menezo as applied to claims 1 and 16 above, and further in view of Skrabanja et al. (reference of record; US Patent 5,929,028).

The teachings of Menezo are described above. Menezo does not teach liquid forms of FSH and hCG supplied in vials or cartridges. Menezo does not teach necessarily teach written instructions.

Skrabanja et al. teach liquid forms of FSH and hCG supplied in vials and cartridges (abstract; column 3, lines 15-30; line 50-column 4, line 30 and column 6, line 56-column 7, line 15)(**applies to claims 17 and 18**). Skrabanja et al. teach that useful doses of gonadotropins are known to medical practioners and the amount included in a dose is generally dependent upon the disease state. Skrabanja et al. teach FSH IU doses from about 25 to 1500, 50-225 and 75 IU. Skrabanja et al. teach that suitable concentrations of FSH ranges from about 20-2000 IU/ml, which roughly corresponds with a concentration of 2-200 ug/ml (column 6, lines 23-41). Skrabanja et al. teach amounts of hCG IU doses as high as 10,000 IU and as low as 15 IU (column 6, lines 22-35). Skrabanja et al. teach a combination of FSH and hCG dissolved together (column 6, lines 42-46).

It would be obvious to one of skill in the art at the time the invention was made to modify the pharmaceutical compositions comprising various IU doses of FSH and hCG as taught by Menezo by formulating it as a liquid pharmaceutical composition comprising various IU doses of FSH and hCG supplied in a vial and/or cartridge as

taught by Skrabanja et al. with a reasonable expectation of success. The motivation and expected success is provided by Menezo and Skrabanja, who both teach formulations comprising various IU doses of FSH and hCG. In addition, Skrabanja et al. teachings of liquid pharmaceutical composition comprising FSH and hCG supplied in vials and/or cartridges provides ready for use injection preparations. Because Menezo and Skrabanja both teach pharmaceutical kits, vials and/or cartridges comprising the gonadotropins, it would be obvious that the pharmaceuticals would have written instructions regarding timing of administering the composition (**applies to claim 20**). Claim 20 does not recite the physical form of the written instructions (i.e. paper, label, disc, etc), thus the references meet the limitation.

Claim 47 is rejected under 35 U.S.C. 103(a) as being unpatentable over Skrabanja et al. in view of Filicori. The teachings of Skrabanja et al. and Filicori et al. are described above.

Skrabanja et al. teach a method of treating infertility by the administration of gonadotropins. Skrabanja et al. teach gonadotropin-containing formulations comprising FSH or hCG or mixtures thereof. Skrabanja et al. teach the use of recombinant FSH and hCG. Skrabanja et al. teach that suitable concentrations of FSH ranges from about 20-2000 IU/ml, which roughly corresponds with a concentration of 2-200 ug/ml. Skrabanja et al. teach that as high as 10,000 IU and as low as 15 IU of hCG have been administered. Skrabanja et al. do not teach the ug concentration of hCG.

Filicori et al. teach the administration of 75-150 IU FSH with 50 IU of Profasi urinary hCG to induce folliculogenesis. Profasi urinary hCG is equivalent to 2.5 ug of recombinant hCG.

It would be obvious to one of skill in the art at the time the invention was made that the pharmaceutical compositions comprising IU doses/concentration of FSH and hCG as taught by Skrabanja et al. and Filicori et al. would overlap to included a product comprising a first pharmaceutical composition comprising FSH in an amount from about 1.0 ug to about 2,000 mg/ml and a second pharmaceutical composition comprising hCG in amount from about 0.1 ug to about 2,000 mg/ml, which works with a reasonable expectation of success. The motivation and expected success is provided by Skrabanja et al. and Filicori et al., who both teach formulations comprising FSH and hCG for treating infertility. Skrabanja et al. teachings of FSH in ranges from about 20-2000 IU/ml, which roughly corresponds with a concentration of 2-200 ug/ml and hCG as high as 10,000 IU and as low as 15 IU of hCG overlap with Filicori et al. teachings of FSH in the range of 75-150 IU with 50 IU hCG.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re*

Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 7, 8, 11-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-16 of **copending Application No. 11/898,470.** Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are drawn to a pharmaceutical composition consisting essentially of similar IU amounts of FSH and hCG and at least one pharmaceutically acceptable carrier. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 1, 7, 8, 11, 13, 49 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 1 of **copending Application No. 11/979,265.** Although the conflicting claims are not identical, they are not patentably distinct from each other because both set of claims are drawn to a pharmaceutical composition consisting essentially of similar IU amounts of FSH and hCG and at least one pharmaceutically acceptable carrier. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571) 272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

/R. M. D./
Examiner, Art Unit 1647

1/15/09